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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,239	12/08/2000	James Blake	02558P-001340US	1694

20350 7590 03/23/2005

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EXAMINER

LE, EMILY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,239

Applicant(s)

BLAKE ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

HL

DETAILED ACTION

Status of Claims

1. Claims 29-47 are cancelled. Claims 1-28 are pending. Claims 14-28 are withdrawn from consideration. Claims 1-13 are under examination.

Priority

2. In view of Applicant's 12/20/04 submission, copendency between 08/462749 and the instant application is noted.

Information Disclosure Statement

3. Part of the information disclosure statement filed 08/29/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because an English translation of reference "AO" is not provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantial portion" in claim 1 is a relative term which renders the claim indefinite. The term "substantial portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Additionally, the claims are indefinite for the following recitation "a substantial portion of the composition comprising the immobilized peptide comprises peptide". It is unclear what is intended by the recitation. As written, it appears that Applicant desires that another peptide be within the immobilized peptide.

Lastly, the claims require that the two Cys residues be reversibly protected from oxidation; and that the two Cys residues have an intramolecular disulfide bond between one another. These two requirements are contradictory to one another. A disulfide bond is a covalent bond formed by the oxidation of two sulfhydryl (SH) groups. Ergo, it is unclear how a disulfide bond can exist between the two Cys residues that are protected from oxidation?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosand et al. (U.S. Patent No. 4629783).

For the purpose of this rejection, in view of the indefiniteness rejection made above for the contradictory requirements present in the claims, the claimed invention is interpreted as directed to:

a composition comprising an isolated peptide immobilized on a solid phase, said peptide having at least one epitope capable of binding antibodies to a protein comprising the epitope; wherein the peptide comprises an amino acid sequence of six to 50 amino acids and the sequence comprises two Cys residues which are separated from each other by at least two but fewer than 20 non-Cys amino acid residues and wherein thiol groups of the Cys residues are reversibly protected from oxidation by a chemically reversible means. The claims require that peptide further comprise a third Cys residue at the N-terminus of the peptide, wherein the third Cys residue is not protected from oxidation; the C-terminus of the peptide be amidated; limits the number of non-Cys residues between the protected Cys residues to 4 to 6 non-Cys residues; requires the peptide be capable of binding antibodies to a retroviral transmembrane protein; which is later limited to SEQ ID NO: 1; requires the peptide to comprise at least seven contiguous amino acids of SEQ ID NO: 1. Additionally, the claims require the Cys residues be protected from oxidation by, acetamidomethyl.

Cosand et al. teaches a composition comprising an isolated peptide immobilized on a solid phase. [Lines 54-64, column 9.] The peptide Cosand et al. teaches is of six to 50 amino acids, specifically 23 and 26 amino acid residues in length. [Peptides of the formula (I) and (V), respectively, wherein peptide of the formula (V) is the same as claimed SEQ ID NO: 1.] The peptide sequence comprises two Cys residues which are separated from each other by at least two but fewer than 20 non-Cys amino acid residues. Specifically, the peptide of the formula (I), the Cys residues are separated from each other by 20 non-Cys amino acid residues; and the peptide of the formula (V), the Cys residues are separated from each other by 5 non-Cys amino acid residues. The thiol groups of the Cys residues are reversibly protected from oxidation by a chemically reversibly mean. [Lines 54-64, column 9.] Both the peptides of Cosand et al. immunologically mimic proteins encoded by the LAV/HTLV-III retrovirus. Cosand et al. also notes that the peptides can be used for detection of the virus or of antibodies to the virus; ergo, the peptide of Cosand et al. comprises at least an epitope capable of binding antibodies to a protein, particularly a retroviral transmembrane protein. [Lines 18-68 of column 2 to lines 1-53 of column 3.] Additionally, Cosand et al. also teaches the addition of a non-protected Cys residue to the N-terminus of the peptide of formula (I). The added non-protected Cys residue, if added to the peptide of formula (I) would be a third Cys residue. The C-terminus of the peptide of Cosand et al. is also amidated. [Lines 14-29 of column 4 and lines 30-39 of column 5.] Additionally, Cosand et al. teaches the attachment of the peptide of formula (I) onto a t-butyloxy-carbonyl (BOCD)-methylbenzylcystein-phenyl-acetaminomethyl polystyrene/divinylbenzene resin.

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Although Cosand et al. is silent on the protection of Cys residues present in peptide of formula (I) with acetamidomethyl; free phenyl-acetamidomethyl ions, including acetamidomethyl would necessarily react with the Cys residues to yield a Cys-acetamidomethyl conjugate. The resulting conjugate would necessarily be protected from oxidation. Cosand et al. teaches the claimed invention. Ergo, Cosand et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosand et al. (U.S. Patent No. 4629783) in view of Brugger et al. (U.S. Patent No. 3798203.).

Claim 3 limits the technique used to protect the Cys residues from oxidation to ethylcarbamoyl.

Cosand et al. et al. teaches protecting Cys residues from oxidation. Cosand et al. does not teach the use of ethylcarbamoyl to protect Cys residues from oxidation. However, the use of ethylcarbamoyl is an art-recognized technique for protecting Cys residues from oxidation, see Brugger et al. Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use a different art-recognized technique for protecting Cys residues from oxidation with a reasonable expectation of success.

10. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being Cosand et al. (U.S. Patent No. 4629783) in view of Neurath et al. (U.S. Patent No. 4861588).

Claims 5 and 12 require that the third Cys residue at the N-terminus of the peptide be Cys-Gly-Gly.

Cosand et al. does not teach the addition of Cys-Gly-Gly to the peptide. Cosand et al. teaches the use of amino acids such as cytosine or the like to provide a useful functionality such as for linking or immobilizing the peptide, by providing an "arm".

Neurath et al. teaches the addition of Cys-Gly-Gly, as a spacer arm, to the N-terminus of a peptide. Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching both Cosand et al. and Neurath et al. to create a peptide with a spacer arm. One of ordinary skill in the art at the time the invention was made would have been motivated to create a peptide with a spacer arm to facilitate the immobilization of the peptide. One of ordinary skill in the art would have had a reasonable expectation of success for making the peptide with a spacer arm because Neurath et al. teaches a peptide with a spacer arm.

11. Claims 10-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosand et al. (U.S. Patent No. 4629783).

Claims 10-11 require that claimed SEQ ID NO: 1 further comprises a third Cys residue, wherein the residue is not protected from oxidation, at the N-terminus of the peptide. Claim 13 requires that the C-terminus of the peptide be amidated.

The teaching of Cosand et al. is noted above. Peptide of formula (V) of Cosand et al. is the same as claimed SEQ ID NO: 1. The C-terminus of the peptide of Cosand et al.

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is amidated. The peptide of Cosand et al. does not have a third Cys residue. However, Cosand et al. suggests the use of the mercaptan group of cysteines for acylating terminal amino groups for linking two peptides by disulfide linkage. Ergo, it would have prima facie obvious for one of ordinary skill in the art at the time the invention was made to add a third Cys residue to the peptide of formula (V). One of ordinary skill in the art would be motivated to add a third Cys residue to the peptide of formula (V) to facilitate the linking of peptides via disulfide linkage. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Cosand et al. suggests the use of the mercaptan group of cysteines for acylating terminal amino groups for linking two peptides by disulfide linkage.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

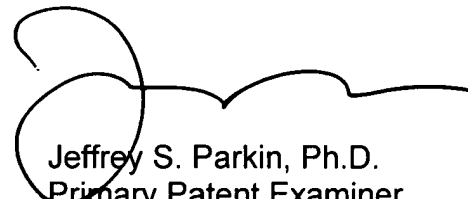
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



E. Le



Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
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